IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	Robert E. Arbogast et al.	Confirm. No.:	4457
Application No.:	09/893,535	Examiner:	Dilek B. Cobanoglu
Filing Date:	06/29/2001	Art Unit:	3626
Title:	System, Method, And Computer Program Product For Configuring And Purchasing A Medical Device	Attorney Docket No.:	OHI 1717-008A

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/Vickie D'Alessandro/
Vickie D'Alessandro (paralegal)

APPELLANTS BRIEF UNDER 37 CFR § 41.37

Dear Sir:

This is an appeal from a final rejection mailed on August 08, 2006, in which the Examiner rejected all of the claims pending in the present application. The requisite $250.00 (small entity) filing fee set forth in 37 CFR § 41.20(b)(2) was previously paid.

REAL PARTY IN INTEREST

Robert E. Arbogast, Michael Edward Hopkins, James M. Colvin, Mark William Ford, Phillip Lee Harrison, Raymond Francis, Keith W. Justus, Rebecca L. Halley, Bradley A. Spitzer, Thomas D. Chamberlain and Eric L. Kershner are currently named as inventors on the present application. The present application has been assigned to the Ohio Willow Wood Company, which is the real party of interest in the present appeal.

RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals, interferences or judicial proceedings that relate to or would in any way affect or have a bearing on the Board's decision in the present appeal.

STATUS OF CLAIMS

Claims 1-39, 46-49, 65-69 and 80-82 are pending in the present application. Claims 1-39, 46-49, 65-69 and 80-82 stand rejected. Claims 40-45, 50-64, 70-79 and 83-85 have been withdrawn from consideration as the result of a previously issued restriction requirement. Claims 1-39, 46-49, 65-69 and 80-82 are the subject of this appeal.

STATUS OF AMENDMENTS

Per the Advisory Action of December 18, 2006, Appellant's November 08, 2006 response to the Examiner's final Office Action mailed on August 08, 2006 was entered for purposes of appeal, along with an explanation as to how the amended claims would be rejected.

SUMMARY OF CLAIMED SUBJECT MATTER

The claimed subject matter is directed to an automated system and method of configuring a medical device, such as a prosthesis, from a collection of individual medical device components. More specifically, based on one or a few criteria (typically patient attributes and/or desires), a system and method of the present invention can query one or more databases containing relevant components, retrieve and sort through the multitudes of components available with respect to a particular medical device (e.g., a prosthetic leg or arm) and provide one or a number of acceptable prosthesis configurations using various combinations of qualifying components. Such criteria may include, for example, patient weight, patient activity level, medical device cost, or medical device weight. Thus, a system and method of the present invention can greatly reduce the time required to configure a medical device – which would currently be accomplished by a practitioner using a number of different catalogues, etc.

Support for the various elements of independent claims 1, 31, 46 and 65, as presented in Appellant's November 08, 2006 response to the Examiner's final Office Action, is identified in the charts below:

Claim 1		
Element Number	*Claim Elements from Claim 1*	*Support in Application*
1	A system for configuring a medical device, comprising:	At least paragraphs [0001], [0016]-[0023], [0039]-[0108]; FIGS. 1-2, 7-8, 10-11.
2	a digital repository populated with entries defining a plurality of medical device components,	At least paragraphs [0041], [0049]-[0050], [0061], [0065] and [0078]; Abstract.

3	each entry associated with an individual medical device component and having	At least paragraphs [0049]-[0050], [0061] and [0065].
4	a component identification indicator,	At least paragraphs [0041], [0049]-[0050], [0061], [0065], [0072] and [0078].
5	a component class indicator, and	At least paragraphs [0065], [0063] and [0078]; FIG. 3.
6	at least one patient attribute indicator;	At least paragraphs [0018]-[0019], [0024], [0057], [0062] and [0083].
7	a processor; and	At least paragraphs [0097], [0100]-[0101], and [0105]-[0106]; FIG. 11.
8	a computer readable medium encoded with processor readable instructions that when executed by the processor implement	At least paragraphs [0098], [0101]-[0103] and [0105]; FIG. 11.
9	a practitioner user interface mechanism configured to provide a practitioner with access to entries in the digital repository via a network and to allow the practitioner to provide at least one patient interview answer indicator,	At least paragraphs [0021], [0039], [0048], [0053]-[0054], [0058]-[0062], [0070], [0077]-[0078], [0089]; FIGS. 1, 9 and 10A-10H.
10	a patient interview mechanism configured to receive over the network the at least one patient interview answer indicator corresponding to an attribute of a patient and to store the at least one patient interview answer indicator in a memory, and	At least paragraphs [0051]-[0052], [0058], [0061]-[0062]; FIGS. 4, 6 and 9.
11	a configurator mechanism configured to select a subset of entries from the digital repository based on the at least one patient interview answer indicator in the memory,	At least paragraphs [0054], [0058], [0068]-[0069], [0071]-[0072]; FIGS. 2, 4, 4A 6 and 9.

12	the subset of entries including entries corresponding to individual medical device components that collectively form a medical device meeting a need of the patient.	At least paragraphs [0005], [0018], [0020], [0024], [0050], [0068]-[0069], [0071]-[0072]; FIGS. 2, 4, 4A 6 and 9.

Claim 31		
Element Number	*Claim Elements from Claim 31*	*Support in Application*
1	A method for configuring a medical device, comprising the steps of:	At least paragraphs [0001], [0016]-[0023], [0039]-[0108]; FIGS. 3-10.
2	populating a digital repository with information corresponding to a plurality of medical device components;	At least paragraphs [0041], [0049]-[0050], [0061], [0065] and [0078]; Abstract.
3	interviewing a patient having a need for a medical device to determine at least one patient attribute;	At least paragraphs [0021], [0051]-[0052], [0061][0062], [0067], [0081], [0090]; FIG. 3.
4	storing the at least one patient attribute in a memory; and	At least paragraphs [0018]-[0019], [0024], [0057], [0062] and [0083].
5	querying the digital repository for a subset of medical device components based on the at least one patient attribute,	At least paragraphs [0054], [0058], [0068]-[0069], [0071]-[0072]; FIGS. 2, 4, 4A, 6 and 9.
6	the subset of medical device components collectively forming a medical device meeting the need of the patient.	At least paragraphs [0005], [0018], [0020], [0024], [0050], [0068]-[0069], [0071]-[0072]; FIGS. 2, 4, 4A, 6 and 9.

Claim 46		
Element Number	*Claim Elements from Claim 46*	*Support in Application*
1	A system for configuring a medical device, comprising:	At least paragraphs [0001], [0016]-[0023], [0039]-[0108]; FIGS. 1-2, 7-8, 10-11.
2	means for populating a digital repository with information corresponding to a plurality of individual medical device components;	At least paragraphs [0041], [0049]-[0050], [0061], [0065] and [0078]; Abstract.
3	means for interviewing a patient having a need for a medical device to determine at least one patient attribute;	At least paragraphs [0021], [0051]-[0052]; FIGS. 1 and 10A.
4	means for storing the at least one patient attribute in a memory; and	At least paragraphs [0018]-[0019], [0024], [0057], [0062], [0083], [0102]-[0103], [0105]-[0106].
5	means for querying the digital repository for a subset of medical device components based on the at least one patient attribute,	At least paragraphs [0054], [0058], [0068]-[0069], [0071]-[0072]; FIGS. 2, 4, 4A, 6 and 9.
6	the subset of medical device components collectively forming a medical device meeting the need of the patient.	At least paragraphs [0005], [0018], [0020], [0024], [0050], [0068]-[0069], [0071]-[0072]; FIGS. 2, 4, 4A, 6 and 9.

Claim 65		
Element Number	*Claim Elements from Claim 65*	*Support in Application*
1	A method for configuring a medical device, comprising the steps of:	At least paragraphs [0001], [0016]-[0023], [0039]-[0108]; FIGS. 3-10.

2	populating a digital repository with information corresponding to a plurality of individual medical device components;	At least paragraphs [0041], [0049]-[0050], [0061], [0065] and [0078]; Abstract.
3	populating the digital repository with patient historical information associated with a patient;	At least paragraphs [0023], [0050], [0072]; Abstract.
4	interviewing the patient having a need for a medical device to determine at least one patient attribute;	At least paragraphs [0021], [0051]-[0052], [0061][0062], [0067], [0081], [0090]; FIG. 3.
5	storing the at least one patient attribute in a memory via a digital communication link;	At least paragraphs [0018]-[0019], [0024], [0043], [0045]-[0046], [0051], [0057], [0062], [0083], [0107]-[0108]; FIGS. 1 and 9.
6	querying the digital repository for a subset of medical device components based on the at least one patient attribute,	At least paragraphs [0054], [0058], [0068]-[0069], [0071]-[0072]; FIGS. 2, 4, 4A, 6 and 9.
7	the subset of medical device components collectively forming a medical device meeting the need of the patient;	At least paragraphs [0005], [0018], [0020], [0024], [0050], [0068]-[0069], [0071]-[0072]; FIGS. 2, 4, 4A, 6 and 9.
8	ordering the medical device over the digital communication link; and	At least paragraphs [0017], [0019], [0024]-[0025], [0029], [0031]-[0032], [0034], [0041], [0062], [0067], [0070], [0076]-[0078], [0085]-[0088]; FIGS. 1, 3-4, 5-6, 10G-10H.
9	storing information corresponding to the medical device in the digital repository associated with the patient.	At least paragraphs [0077], [0085], [0088].

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 31-37, 39, 46-48, 65-67 and 82 are unpatentable under 35 U.S.C. § 102(e) in view of Clynch (US 6,463,351);

2. Whether claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81 are unpatentable under 35 U.S.C. § 103(a) over Clynch (US 6,463,351) in view of DeBusk et al. (US 6,581,204);

3. Whether claims 38 and 49 are unpatentable under 35 U.S.C. § 103(a) over Clynch (US 6,463,351) in view of Vanker et al. (US 2002/0099631 A1);

4. Whether claims 68 and 69 are unpatentable under 35 U.S.C. § 103(a) over Clynch (US 6,463,351) in view of Haller et al. (US 2001/0051787 A1);

5. Whether claims 6 and 7 are unpatentable under 35 U.S.C. § 103(a) over Clynch (US 6,463,351) and DeBusk et al. (US 6,581,204) in further view of Vanker et al. (US 2002/0099631 A1); and

6. Whether claims 15, 17, 18 and 21 are unpatentable under 35 U.S.C. § 103(a) over Clynch (US 6,463,351) and DeBusk et al. (US 6,581,204) in further view of Haller et al. (US 2001/0051787 A1).

ARGUMENT

Rejection of Claims 31-37, 39, 46-48, 65-67 and 82 Under 35 U.S.C. § 102(e)

The Examiner rejected claims 31-37, 39, 46-48, 65-67 and 82 under 35 U.S.C. § 102(e) as being anticipated by Clynch (US 6,463,351). Appellants respectfully disagree with the Examiner's rejection of said claims.

Clynch does not teach the subject matter of the rejected claims. Rather, Clynch is directed specifically and only to producing an individual custom prosthetic socket or

other similar *interface component*. Specifically, Clynch teaches an improved system and method for producing a customized interface (e.g., socket) for a prosthetic or orthotic device. The specific steps required to produce such a socket were set forth in Appellants' November 08, 2006 response to the Examiner's final Office action and can be found in Clynch at col. 2, ll. 28-48; col. 2, line 58 - col. 3, line 26; claim 1; and Figure 1. Therefore, Clynch teaches only the manufacturing of an individual prosthetic component, not the configuring, producing or assembling of a complex medical device (e.g., prosthesis or orthosis) from a *collection* of *individual* medical device *components*.

While Clynch does teach a method for manufacturing a prosthetic socket, it fails to teach a new method for designing, configuring or assembling the remainder of a prosthesis (of which the Clynch interface is merely a part). Rather, the remainder of the prosthesis or orthosis must still be configured by a known manual method like the present invention is specifically designed to render obsolete. That is, once a prosthetist, orthotist or other practitioner uses the system and method of Clynch to obtain a customized prosthetic or orthotic socket, the prosthetist/orthotist must still manually search for the remainder of the components required to assemble the overall prosthesis or orthosis from a variety of catalogs and other sources and then manually sort through a potentially enormous number of possible combinations of said components to arrive at one or several acceptable configurations. It is this type of manual process that the method of the rejected claims renders obsolete.

That is, based on one or a few criteria, a system and method of the present invention can sort through one or more databases containing the multitudes of

components available with respect to a particular prosthesis type (e.g., leg, arm) or other medical device type and provide one or a number of acceptable prosthesis or other medical device configurations using various combinations of qualifying components. Such criteria may include, for example, a prosthesis of the lowest cost or of the lightest weight, and/or may be based on patient-specific data such as weight, activity level, etc.

In this regard, Appellants further assert that Clynch also fails to teach the interviewing of a patient. Clynch teaches only that a practitioner interacts with a patient during the casting and scanning of the patient's residual limb. There is no teaching that the practitioner interviews the patient, formally or otherwise, to obtain at least one patient attribute that will be subsequently used in the configuration and selection of a prosthesis. Rather, the Examiner merely infers that this is likely. Appellants disagree.

Throughout the prosecution of the present application, the Examiner has continued to assert that particular sections of Clynch teach the claimed aspects of the present invention. Appellants have, on several occasions, made known to the Examiner that they have been unable to locate support for the Examiner's assertions at the cited locations of Clynch. These concerns have not, however, been adequately addressed by the Examiner. For example, the following discrepancies were pointed out in Appellants' November 08, 2006 response to the Examiner's final Office action:

- With respect to independent claim 31 of the present application, the Examiner asserts that the claimed subject matter

querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient

is taught by Clynch at col. 7, ll. 22-44 and 61-65, as well as col. 4, ll. 14-39 thereof. However, Clynch at column 4 merely describes that prosthetists, orthopedic surgeons, podiatrists, radiologists and plastic surgeons may practice *the invention* in creating prosthetic devices, orthotic devices, etc. This is no doubt true - but the *invention* of Clynch is the creation of a custom medical device *interface*, not an overall prosthesis. Thus, in order to configure the remainder of the medical device, these practitioners are currently forced to employ the manual system that the present invention renders obsolete. Further, Appellants have been unable to locate any reference to a subset of medical device components, a digital repository, or the querying of a digital repository anywhere in the cited portion of column 4.

Similarly, there is absolutely no mention of a subset of medical device components, a digital repository of medical device components, or querying a digital repository for a subset of medical device components in column 7, ll. 22-44 or 61-65 of Clynch. By referring to line 14 of column 7, it is clear that the language cited by the Examiner describes only the digital image manipulation portion of the Clynch invention. (See also Fig. 3, referred to therein). Everything described in these sections of Clynch, and shown in Fig. 3, is related to a practitioner manipulating the digital image of the cast body part to produce areas of relief or build-up in the subsequently manufactured

interface component. (See col. 1, ll. 33-38 for more general description). The referenced shrink and smooth operations, as well as the database storage of default modifications (i.e., pre-defined image changes), are all functions of image manipulation. Even the language of lines 47-52 refers to modifications that may be made to the *digital image* in order to produce specific modifications to the finished interface component in the stated areas - *not* to *medical device components*. There is no discussion of a digital repository of medical device components, because Clynch is not concerned with anything more than a single component at a time. Further, the database referred to by the Examiner stores only information on previous changes made to similar digital body part (model) images, not information on medical devices.

- With respect to independent claim 46 of the present application, the Examiner makes the same assertions discussed above with respect to claim 31, and further asserts that the claimed subject matter

> *means for populating a digital repository with information corresponding to a plurality of individual medical device components*

is taught by Clynch at col. 4, ll. 14-39 and 49-53; and col. 7, ll. 61-63 thereof. The lack of any such disclosure at col. 4, ll. 14-39 and col. 7, ll. 61-63 of Clynch has already been addressed above. Col. 4, ll. 49-53 of Clynch is similarly lacking in such teachings. Rather, this section of Clynch discloses only that a scan facility may be equipped with equipment that allows for the capturing (via scanning) of a 3-dimensional image of a target (body part) surface, and for conversion of the scanned data into a 3-dimensional image (see Fig. 3) that may be displayed on a computer. Once again, the cited sections

of Clynch appear to be wholly devoid of any reference to a *digital repository* or to *medical device components*.

- The Examiner makes the same assertions with respect to independent claim 65 as were made with respect to claim 46. As the deficiencies of these cited sections have already been discussed above, there is no need to repeat the arguments here.

As can be understood from the foregoing, Clynch fails to teach at least several elements of each of the rejected claims. Consequently, Appellants once again respectfully submit that Clynch cannot support a rejection of claims 31-37, 39, 46-48, 65-67 and 82 under 35 U.S.C. § 102(e).

Rejection of Claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81 35 U.S.C. § 103(a)

The Examiner rejected claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81 under 35 U.S.C. § 103(a) as being unpatentable over Clynch in view of DeBusk et al. (US 6,581,204). Appellants respectfully disagree with the Examiner's rejection of said claims.

Most of the deficiencies of Clynch combined with DeBusk et al. have already been addressed above. DeBusk et al. appears to be nothing more than an advanced medical supply inventory tracking and management system and, as such, does nothing to make up for the above-documented deficiencies of Clynch. In fact, the Examiner appears to have cited DeBusk et al. only for its asserted disclosure of a component identification indicator. Therefore, with respect to independent claim 1, Clynch in view of DeBusk et al. fails to teach or suggest at least:

(1) a digital repository populated with entries defining a plurality of medical device *components*, the entries each associated with an *individual* medical device component;

(2) at least one *patient attribute indicator* associated with the entries;

(3) *a practitioner user interface mechanism* configured to provide a practitioner with access to entries in the digital repository via a network and to allow the practitioner to provide at least one *patient interview answer indicator*;

(4) *a patient interview mechanism* configured to receive over the network the at least one patient interview answer indicator corresponding to an attribute of a patient and to *store the at least one patient interview answer indicator in a memory*; and

(5) *a configurator mechanism* configured to *select a subset of entries from the digital repository* based on the at least one patient interview answer indicator in the memory, the subset of entries including entries *corresponding to individual medical device components* that *collectively* form a medical device meeting a need of the patient.

Furthermore, as discussed with respect to the previous rejection, the Examiner has continued to cite sections of Clynch in which Appellants have been unable to find various allegedly present subject matter. For example, the following specific discrepancies were pointed out in Appellants' November 08, 2006 response to the Examiner's final Office action with respect to claim 1:

- With respect to independent claim 1 of the present application, the Examiner asserts that the claimed subject matter

> *a digital repository populated with entries defining a plurality of medical device components, each entry associated with an individual medical device component*

is taught by Clynch at col. 4, ll. 14-39 and lines 49-53 as well as col. 7, line 61 to col. 8, line 10 thereof, and that the claimed subject matter

> *a configurator mechanism configured to select a subset of entries from the digital repository based on the at least one patient interview answer indicator in the memory, the subset of entries including entries corresponding to individual medical device components that collectively form a medical device meeting a need of the patient*

is taught by Clynch at col. 7, ll. 22-44 and 61-65. The teachings of Clynch at column 4, ll. 14-39 and lines 49-53 have been previously addressed. Clynch at col. 7, line 61 to col. 8, line 10, merely expounds slightly on the digital image manipulation discussion described above. The digital image manipulation of Clynch is in no way related to the *sorting and selection* of multiple medical device components contemplated by the present invention. The cited sections of Clynch, like the remainder of said reference, are simply devoid of such teaching or suggestion, and the Examiner does not appear to have cited Debusk in the rejection of claim 1.

As with the previous rejection, Clynch in view of DeBusk et al. fails to teach at least several elements of each of the rejected claims. Therefore, Appellants once again respectfully submit that Clynch in view of DeBusk et al. cannot support a rejection of claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81 under 35 U.S.C. § 103(a).

Rejection of Claims 38 and 49 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 38 and 49 under 35 U.S.C. § 103(a) as being unpatentable over Clynch in view of Vanker et al. (US 2002/0099631 A1). Appellants have previously explained the allowability of independent claims 31 and 46. As such, claims 38 and 49, which depend respectively therefrom, are also allowable.

Rejection of Claims 68 and 69 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 68 and 69 under 35 U.S.C. § 103(a) as being unpatentable over Clynch in view of Haller et al. (US 2001/0051787 A1). Appellants have previously explained the allowability of independent claim 65. As such, claims 68 and 69, which depend respectively therefrom, are also allowable.

Rejection of Claims 6 and 7 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Clynch in view of DeBusk et al. in further view of Vanker et al. Appellants have previously explained the allowability of independent claim 1. As such, claims 6 and 7, which depend respectively therefrom, are also allowable.

Rejection of Claims 15, 17, 18 and 21 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 15, 17, 18 and 21 under 35 U.S.C. § 103(a) as being unpatentable over Clynch in view of DeBusk et al. in further view of Haller et al. Appellants have previously explained the allowability of independent claim 1. As such, claims 15, 17, 18 and 21, which depend respectively therefrom, are also allowable.

Other Discrepancies

In addition to the discrepancies already pointed out above with respect to the cited sections of Clynch, Appellants also disagree with the Examiner's reliance on the following sections of Clynch and assert that the language thereof does not support the Examiner's conclusions:

- in paragraph 11, the "body portions" referred to by the Examiner are human body portions that may be scanned and imaged according to the invention of Clynch. They are *not* medical devices *nor* medical device *components* and, thus, they are not relevant to the present invention;

- in paragraph 12, the patellar tenon bar, head of fibula and posterior wall extension referred to by the Examiner as "medical components" and appearing in col. 7, ll. 44-52 of Clynch, are in actuality various anatomical features of an amputated lower leg. These are human body part features, *not* "medical components";

- in paragraph 13, the tubular modeling material referred to by the Examiner is not a medical device or a medical device component. Rather, the modeling material is a casting material that is temporarily placed on a patient's body part to produce the 3-dimensional model that is eventually scanned, digitized and manipulated. As the modeling material does not remain on the patient's body, nor become part of the resulting interface component (socket), there would be no reason for the practitioner or anyone else to ask the patient whether the tubular modeling material is comfortable or suits the patient's lifestyle (as seems to be asserted by the Examiner);

- in paragraph 14, the scan data file referred to by the Examiner is not a stored patient attribute (weight, height, activity level, prosthesis weight preference, etc.). Rather, the file the Examiner refers to is simply a *saved digital image of the cast model*, either before or after manipulation by a practitioner;

- in paragraph 15, Appellants reassert the same argument: operating a CAD software package to manipulate a 3-dimensional image of a body part (i.e., to produce areas of build-up or relief in the finished interface component) is clearly not the same as *querying a database of medical device components* in relation to selecting acceptable components for the construction of a prosthesis. Shape/size manipulation of a 3-dimensional image is simply not the same as, or even related to, sorting and selectively choosing components from a database of components based on predetermined criteria;

- in paragraph 16, Appellants again stress that this section of Clynch teaches only that an *interface component* created according to the described *invention* may be subsequently used in the assembly of, e.g., a prosthesis or orthosis. However, it is not taught or suggested that the invention can be used to create an overall prosthesis or orthosis. Rather, the manual configuration technique that the present invention seeks to render obsolete would have to be practiced in conjunction with Clynch in order to create a complete prosthesis or orthosis. Further, the invention of Clynch is directed *only* to the interface *component* of such a device. As the remainder of such a device does not contact the patient, it should be obvious that the invention of Clynch would not be applicable to other components; and

- in paragraph 21, the pull down menu options referred to by the Examiner are nothing more than menus that allow for a practitioner to perform particular manipulations of the 3-dimensional digital image of the modeled body part (much like the pull down menus of any CAD software package allow for the specific manipulation of a drawing model). Contrary to the Examiner's belief, these menus nor the software associated therewith, have anything whatsoever to do with *selecting a subset of medical device components from a digital repository* thereof.

CONCLUSION

For at least the foregoing reasons, it is submitted that the Examiner's rejection of claims 1-39, 46-49, 65-69 and 80-82 is unsupported by the cited references. As such, reversal of the Examiner's rejection of claims 1-39, 46-49, 65-69 and 80-82 and allowance of the present application is respectfully requested.

Respectfully submitted,

Date: 06-18-2007

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CLAIMS APPENDIX

(as appearing in Appellants' November 08, 2006 response)

Claim 1 (previously presented): A system for configuring a medical device, comprising:

a digital repository populated with entries defining a plurality of medical device components, each entry associated with an individual medical device component and having

a component identification indicator,

a component class indicator, and

at least one patient attribute indicator;

a processor; and

a computer readable medium encoded with processor readable instructions that when executed by the processor implement

a practitioner user interface mechanism configured to provide a practitioner with access to entries in the digital repository via a network and to allow the practitioner to provide at least one patient interview answer indicator,

a patient interview mechanism configured to receive over the network the at least one patient interview answer indicator corresponding to an attribute of a patient and to store the at least one patient interview answer indicator in a memory, and

a configurator mechanism configured to select a subset of entries from the digital repository based on the at least one patient interview answer indicator in the memory, the subset of entries including entries corresponding to individual medical device components that collectively form a medical device meeting a need of the patient.

Claim 2 (original): The system of Claim 1, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device.

Claim 3 (original): The system of Claim 1, wherein:

the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement a customization mechanism configured to at least one of add, remove, and modify at least one entry of the subset of entries selected by the configurator mechanism, and the practitioner user interface mechanism is further configured to provide access to the customization mechanism.

Claim 4 (original): The system of Claim 3, wherein the practitioner user interface mechanism is further configured to provide a summary page of components customized by the customization mechanism.

Claim 5 (original): The system of Claim 1, wherein:

the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement a medical device shopping mechanism configured to place an order for the medical device and to store order information in the digital repository, and

the practitioner user interface mechanism is further configured to provide access to the medical device shopping mechanism.

Claim 6 (original): The system of Claim 5, wherein the medical device shopping mechanism is further configured to determine all applicable price discounts for the medical device available to the practitioner.

Claim 7 (original): The system of Claim 1, wherein at least a portion of the practitioner user interface mechanism is accessible via a personal data assistant.

Claim 8 (original): The system of Claim 1, wherein at least a portion of the network comprises an Internet protocol based network.

Claim 9 (original): The system of Claim 1, wherein a least a portion of the network is the Internet.

Claim 10 (original): The system of Claim 1, wherein the digital repository comprises:

a central digital repository, and

a practitioner local digital repository remote from the central database.

Claim 11 (original): The system of Claim 10, wherein:

at least one of the practitioner local digital repository and the central digital repository is further populated with patient historical entries, the patient historical entries each associated with an individual patient and having a patient identification indicator, and at least one patient history indicator.

Claim 12 (original): The system of Claim 11, wherein the at least one patient history indicator comprises information corresponding to a medical device of the individual patient.

Claim 13 (original): The system of Claim 12, wherein the information corresponding to a medical device of an individual patient comprises an identification number of a component of the medical device.

Claim 14 (original): The system of Claim 11, wherein:

the patient historical entries further have at least one patient care indicator.

Claim 15 (original): The system of Claim 14, wherein the patient care indicator comprises reimbursement information.

Claim 16 (original): The system of Claim 15, wherein the reimbursement information comprises an L code indicator.

Claim 17 (original): The system of Claim 11, wherein the digital repository is configured to interface with an external system.

Claim 18 (original): The system of Claim 17, wherein the external system comprises at least one of a patient management system, a billing system, and an insurance reimbursement system.

Claim 19 (original): The system of Claim 1, wherein:

the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement a patient letter of necessity generation mechanism configured to generate a letter of necessity for the patient based on information stored in the digital repository and to store the letter of necessity in the digital repository, and

the practitioner user interface mechanism is further configured to provide access to the patient letter of necessity generation mechanism.

Claim 20 (original): The system of Claim 1, wherein the digital repository comprises a database.

Claim 21 (original): The system of Claim 1, wherein the practitioner user interface is further configured to accept the at least one patient interview answer indicator from an external device.

Claim 22 (original): The system of Claim 21, wherein the external device is at least one of a digitizer, a digital camera, and a digital video camera.

Claim 23 (original): The system of Claim 1, wherein:

the entries in the digital repository further have a ranking indicator, and

the configurator mechanism is further configured to select a plurality of subsets of entries from the digital repository based on the at least one patient interview answer indicator in the memory, each of the plurality of subsets including entries corresponding to individual medical device components of a medical device meeting the need of the patient and being ranked based on the ranking indicator of the entries.

Claim 24 (original): The system of Claim 23, wherein the ranking indicator comprises at least one of a component cost indicator, a component weight indicator, a component height indicator, a component width indicator, a component activity level indicator, and an inventory indicator.

Claim 25 (original): The system of Claim 23, wherein:

the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement a customization mechanism configured to select one of the plurality of subsets of entries and at least

one of add, remove, and modify at least one entry of the one of the plurality of subsets of entries selected by the configurator mechanism, and

the practitioner user interface mechanism is further configured to provide access to the customization mechanism.

Claim 26 (original): The system of Claim 25, wherein:

the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement a medical device shopping mechanism configured to place an order for the medical device corresponding to the one of the plurality of subsets of entries selected by the customization mechanism and to store order information in the digital repository, and

the practitioner user interface mechanism is further configured to provide access to the medical device shopping mechanism.

Claim 27 (original): The system of Claim 25, wherein the practitioner user interface mechanism is further configured to provide a summary page of components customized by the customization mechanism.

Claim 28 (previously presented): The system of Claim 1, wherein:

the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement a catalog mechanism configured to select a subset of entries from the digital repository based on a query and to provide the subset of entries to the practitioner user interface mechanism, and

a medical device component shopping mechanism is configured to place an order for a medical device component corresponding to at least one selected entry of the subset of entries and to store order information in the digital repository,

the practitioner user interface mechanism further configured to accept the query from a user, to provide the query to the catalog mechanism, and to select the at least one selected entry of the subset of entries provided by the catalog mechanism.

Claim 29 (original): The system of Claim 28, wherein:

the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement a customization mechanism configured to select at least one of the subsets of entries and at least one of add, remove, and modify at least one entry of the one of the plurality of subsets of entries selected by the catalog mechanism, and

the practitioner user interface mechanism is further configured to provide access to the customization mechanism.

Claim 30 (original): The system of Claim 29, wherein the practitioner user interface mechanism is further configured to provide a summary page of components customized by the customization mechanism.

Claim 31 (previously presented): A method for configuring a medical device, comprising the steps of:

populating a digital repository with information corresponding to a plurality of medical device components;

interviewing a patient having a need for a medical device to determine at least one patient attribute;

storing the at least one patient attribute in a memory; and

querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient.

Claim 32 (original): The method of Claim 31, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device.

Claim 33 (original): The method of Claim 31, further comprising the step of:

customizing at least one of the subset of medical device components to create a customized medical device further meeting the need of the patient.

Claim 34 (original): The method of Claim 31, wherein the querying step comprises:

querying the digital repository for a plurality of subsets of medical device components based on the at least one patient attribute, the subset of medical device components corresponding to a medical device meeting the need of the patient; and

ranking the plurality of subsets based on a ranking criteria.

Claim 35 (original): The method of Claim 34, wherein the ranking criteria is at least one of a weight of the medical device, a height of the medical device, a width of the medical device, a cost of the medical device, an activity level supported by the medical device, and an inventory status of the medical device.

Claim 36 (original): The method of Claim 34, further comprising the step of:

selecting one of the plurality of subsets;

customizing the one of the plurality of subsets to create a customized medical device further meeting the need of the patient; and

ordering the customized medical device.

Claim 37 (original): The method of Claim 36, wherein the ordering step comprises reviewing the customized medical device prior to ordering.

Claim 38 (original): The method of Claim 36, wherein the ordering step comprises determining all applicable price discounts for the medical device for the practitioner.

Claim 39 (original): The method of Claim 31, wherein the interviewing step comprises entering the at least one patient attribute via at least one of a personal data assistant, a digitizer, a digital camera, and a digital video camera.

Claim 40 (withdrawn): A method for outsourcing the fabrication of a medical device, comprising the steps of:

populating a digital repository with information corresponding to a plurality of medical device components;

interviewing a patient having a need for a medical device to determine at least one patient attribute;

measuring a body part of the patient and producing a digital map of the body part; and

querying the digital repository by a supplier for a subset of medical device components based on the at least one patient attribute, the subset of medical device components corresponding to a medical device meeting the need of the patient.

Claim 41 (withdrawn): The method of Claim 40, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device.

Claim 42 (withdrawn): The method of Claim 40, further comprising the step of:

sending the at least one patient attribute and the digital map to the supplier over a digital communication link.

Claim 43 (withdrawn): The method of Claim 40, further comprising the step of:

customizing the medical device by the supplier based on the digital map to produce a customized medical device.

Claim 44 (withdrawn): The method of Claim 42, wherein at least a portion of the digital communication link comprises the Internet.

Claim 45 (withdrawn): The method of Claim 42, further comprising the step of:

shipping the customized medical device to the practitioner.

Claim 46 (previously presented): A system for configuring a medical device, comprising:

means for populating a digital repository with information corresponding to a plurality of individual medical device components;

means for interviewing a patient having a need for a medical device to determine at least one patient attribute;

means for storing the at least one patient attribute in a memory; and

means for querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient.

Claim 47 (original): The system of Claim 46, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device.

Claim 48 (original): The system of Claim 46, further comprising:

means for customizing at least one of the subset of medical device components to create a customized medical device further meeting the need of the patient.

Claim 49 (original): The system of Claim 46, further comprising:

means for determining applicable discounts for the medical device for the practitioner.

Claim 50 (withdrawn): A computer program product, comprising:

a computer storage medium and a computer program code mechanism embedded in the computer storage medium for causing a processor to facilitate the management of a digital workflow, the computer program code mechanism having

a first computer code device configured to populate a digital repository with data that is descriptive of components of a medical device,

a second computer code device configured to collect patient information and to store patient specific information in a memory, and

a third computer code device configured to select a subset of components stored in the digital repository based on the patient specific information so as to configure a medical device meeting a need of a particular patient.

Claim 51 (withdrawn): The computer program product of Claim 50, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device.

Claim 52 (withdrawn): The computer program product of Claim 50, wherein:

the first computer code device is further configured to populate ranking information associated with the components of a medical device in the digital repository corresponding to a ranking criteria; and

the third computer code device is further configured to select a plurality of subsets of components stored in the digital repository based on the patient specific information and to rank the plurality of subsets based on the ranking criteria so as to configure a plurality medical devices meeting the need of a particular patient.

Claim 53 (withdrawn): The computer program product of Claim 50, further comprising:

a fourth computer code device configured to customize at least one component of the subset of components selected by the third computer code device.

Claim 54 (withdrawn): The computer program product of Claim 52, further comprising:

a fourth computer code device configured to customize at least one component of one of the plurality of subsets of components selected by the third computer code device.

Claim 55 (withdrawn): The computer program product of Claim 50, further comprising:

a fourth computer code device configured to accept an order for the medical device over a digital communication link.

Claim 56 (withdrawn): The computer program product of Claim 55, wherein at least a portion of the digital communication link is the Internet.

Claim 57 (withdrawn): The computer program product of Claim 50, wherein:

the second computer code device is further configured to store the patient specific information in the memory over a digital communication link.

Claim 58 (withdrawn): The computer program product of Claim 57, wherein at least a portion of the digital communication link is the Internet.

Claim 59 (withdrawn): The computer program product of Claim 50, wherein:

the second computer code device is further configured to collect patient information via at least one of a personal data assistant, a personal computer, a digitizer, a digital camera, and a digital video camera.

Claim 60 (withdrawn): The computer program product of Claim 50, further comprising:

a fourth computer code device configured to provide an interface to an external system, wherein the first computer code device is further configured to populate patient historical information associated with a particular patient.

Claim 61 (withdrawn): The computer program product of Claim 59, wherein the patient historical information comprises an identification number of a component of a medical device of the patient.

Claim 62 (withdrawn): The computer program product of Claim 60, wherein:

the patient historical information comprises patient care information, and

the external system comprises at least one of a patient management system, a billing system, and an insurance reimbursement system.

Claim 63 (withdrawn): The computer program product of Claim 62, wherein the patient care information comprises at least one of reimbursement information and L code information.

Claim 64 (withdrawn): The computer program product of Claim 55, wherein the fourth computer code device is further configured to determine applicable discounts for the medical device for the practitioner.

Claim 65 (previously presented): A method for configuring a medical device, comprising the steps of:

populating a digital repository with information corresponding to a plurality of individual medical device components;

populating the digital repository with patient historical information associated with a patient;

interviewing the patient having a need for a medical device to determine at least one patient attribute;

storing the at least one patient attribute in a memory via a digital communication link;

querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient;

ordering the medical device over the digital communication link; and

storing information corresponding to the medical device in the digital repository associated with the patient.

Claim 66 (original): The method of Claim 65, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device.

Claim 67 (previously presented): The method of Claim 65, wherein the patient historical information comprises at least one of reimbursement information and L code information.

Claim 68 (original): The method of Claim 65, further comprising the step of:

sharing information in the digital repository with an external system.

Claim 69 (original): The method of Claim 68, wherein the external system comprises at least one of a patient management system a billing system, and an insurance reimbursement system.

Claim 70 (withdrawn): A system for collecting data for use in configuring a medical device, comprising:

a digital repository populated with entries defining patient interview questions, the entries each associated with a medical device type and having

a medical device type indicator, and

at least one patient interview question indicator;

a processor; and

a computer readable medium encoded with processor readable instructions that when executed by the processor implement a patient interview mechanism configured to

provide a practitioner with access to entries in the digital repository,

allow the practitioner to provide at least one patient interview answer indicator corresponding to a patient interview question, and

store the at least one patient interview answer in a memory.

Claim 71 (withdrawn): The system of Claim 70, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device.

Claim 72 (withdrawn): The system of Claim 70, wherein at least a portion of the patient interview mechanism is accessible via a personal data assistant.

Claim 73 (withdrawn): The system of Claim 70, wherein the digital repository comprises a database.

Claim 74 (withdrawn): The system of Claim 70, wherein the patient interview mechanism is further configured to accept the at least one patient interview answer indicator from an external device.

Claim 75 (withdrawn): The system of Claim 74, wherein the external device is at least one of a digitizer, a digital camera, and a digital video camera.

Claim 76 (withdrawn): A method for collecting data for use in configuring a medical device, comprising the steps of:

populating a digital repository with information corresponding to a plurality of patient questions related to configuring a medical device;

interviewing a patient having a need for a medical device to determine at least one patient attribute; and

storing the at least one patient attribute in a memory.

Claim 77 (withdrawn): The method of Claim 76, wherein the interviewing step comprises inputting the at least one patient attribute via a personal data assistant.

Claim 78 (withdrawn): The method of Claim 76, wherein the interviewing step comprises entering the at least one patient attribute via at least one of a digitizer, a digital camera, and a digital video camera.

Claim 79 (withdrawn): The method of Claim 76, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device.

Claim 80 (original): The system of Claim 3, wherein:

the customization mechanism is further configured to store a customization result in the digital repository indicating a change made to the subset of entries selected by the configurator mechanism, and

the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implements an algorithm adjustment mechanism configured to adjust an algorithm of the configurator mechanism based on the customization result stored in the digital repository, the adjustment

causing the configurator mechanism to select a different subset of entries based on the at least one patient interview answer indicator.

Claim 81 (original): The system of Claim 80, wherein the algorithm adjustment mechanism comprises an application of artificial intelligence.

Claim 82 (original): The method of Claim 31, further comprising the steps of:

customizing at least one of the subset of medical device components to create a customized medical device further meeting the need of the patient;

storing a customization result of the customizing step in the digital repository;

comparing the customization result to the subset of medical device components to identify a customization trend; and

adjusting an algorithm used in the querying step based on the customization trend causing a different subset of medical device components to be queried based on the at least one patient attribute.

Claim 83 (withdrawn): The computer program product of Claim 53, further comprising:

a fifth computer code device configured to adjust an algorithm of the third computer code device based on a result of the fourth computer code device, the adjustment causing the third computer code device to select a different subset of components based on the patient specific information.

Claim 84 (withdrawn): The computer program product of Claim 83, wherein the result of the fourth computer code device is stored in the digital repository.

Claim 85 (withdrawn): The computer program product of Claim 83, wherein the fifth computer code device comprises an application of artificial intelligence.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

There are no other proceedings relating to the present appeal.